

REMARKS

This Amendment rewrites claim 12. Claims 8-16 are pending.

Entry of this Amendment is earnestly requested, as it is believed (1) to place the application in condition for allowance, (2) not to raise any new issue or require further search, (3) to be directly responsive to the Final Rejection, and (4) to place the application in even better form for appeal, should such appeal be necessary.

The 35 U.S.C. § 103(a) rejection of claims 8-16 over U.S. Patent No. 5,858,280 to Zhang et al. in view of U.S. Patent No. 5,804,318 to Pinchuk et al. is respectfully traversed. The claimed invention is a biodegradable silica xerogel composition comprising a silica xerogel which is capable of controlled release of a biologically active agent, and its method of preparation. In this regard, method claim 12 has been amended by replacing the transitional phrase "comprising" with -- consisting essentially of -- in response to the Patent Office argument that "comprising" permitted the presence and use of additional compounds disclosed in the prior art.

The cited combination of references fails to raise a prima facie case of obviousness against the claimed composition and method. Zhang et al. fails to disclose or suggest a biodegradable silica xerogel composition which can be used for the controlled

release of a biologically active agent. Instead, Zhang et al. teaches a transparent silica gel, useful as a host material for doping optically functional molecules. As previously noted, the metal complexes taught by Zhang et al. in the production of its gel appear unsuitable for medical use.

It is respectfully submitted that the Patent Office argument that "future intended use" has no patentable weight in composition claims is properly limited to an anticipation rejection, and is not applicable to an obviousness rejection. The intended use of a composition is certainly a factor in determining whether one of ordinary skill in the art would consider a particular modification of a prior art composition or method of manufacture. In this case, one of ordinary skill in the art, seeking to develop a silica xerogel composition for controllably releasing a biologically active agent such as heparin would not be consider catalytic compounds which are unsuitable for medical use.

Pinchuk et al. also fails to disclose or suggest the claimed silica xerogel composition. Instead, Pinchuk et al. discloses a surface coating comprising a hydrogel containing pendant amine groups (Col. 3, lines 26-29). The hydrogel is adhered to a surface to be coated by using, for example, a silane priming or coupling agent (Col. 4, line 27). The silane agent is therefore to be used only for silylation of the surface of the material to be coated,

and thus the coating itself is not made of sol-gel derived silica xerogel derived from tetraalkoxysilane, as in the present invention. This is evident from Col. 5, lines 13-15, which teach that the quaternary ammonium cation-containing surface is rendered non-thrombogenic.

Pinchuk et al. fails to disclose or suggest that an anti-thromogenic agent such as heparin can be encapsulated into sol-gel derived xerogel derived from tetraalkoxysilane which has been co-hydrolyzed with an organomodified alkoxysilane, or that heparin may be controllably released from the xerogel.

Reconsideration and withdrawal of the obviousness rejection of claims 8-16 over Zhang et al. in view of Pinchuk et al. are earnestly requested.

The 35 U.S.C. § 103(a) rejection of claims 8-11 over Kuncova et al., 60 Collect.Czech.Chem.Comm. 1573 (1995) in view of Pinchuk et al. is respectfully traversed. The inventors have discovered a composition comprising a silica xerogel which is capable of controlled release of a biologically active agent.

The cited combination of references fails to raise a prima facie case of obviousness against the claimed composition because the references cannot be combined as suggested by the Patent Office. More specifically, Kuncova et al. teaches the immobilization of a biologically active material (lipase) in a sol-

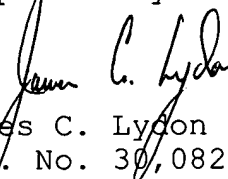
gel silica matrix. One of ordinary skill in the art would not combine Kuncova et al. with Pinchuk et al., which teaches release of a biologically active material (heparin) from its xerogel (Col. 5, lines 16-18).

Reconsideration and withdrawal of the obviousness rejection of claims 8-11 over Kuncova et al. in view of Pinchuk et al. is respectfully requested.

It is believed the application is in condition for allowance. Reconsideration and withdrawal of all rejections of claims 8-16, and issuance of a Notice of Allowance directed to those claims, are earnestly requested. The Examiner is urged to telephone the undersigned should she believe any further action is required for allowance.

It is not believed that any fee is required for entry and consideration of this Amendment. Nevertheless, the Commissioner is authorized to charge our Deposit Account No. 50-1258 in the amount of any such fee deemed necessary for such entry and consideration.

Respectfully submitted,


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